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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/181,671 10/29/98 MEISEL

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HM22/0526

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EXAMINER

DAVIS, B

ART UNIT

PAPER NUMBER

1621

DATE MAILED:

05/26/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/181,671

Applicant(s)
Meisel et al.

Examiner
Brian J. Davis

Group Art Unit
1621



☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-3, 15, and 16 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-3, 15, and 16 is/are rejected.

☒ Claim(s) 3 and 15 is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☒ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☒ received in Application No. (Series Code/Serial Number) 09/004,926.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Drawings

1. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Specification

2. The disclosure is objected to because of the following informalities: use of the Latin abbreviation '[sic]' in the text. Its use on page 4 lines 6 and 37, page 5 lines 26 and 27, page 6 line 15, page 7 lines 22 and 24 and page 9 line 28 introduces an unacceptable ambiguity. Appropriate correction is required.

Claim Objections

3. Claims 3 and 15 are objected to because of the following informalities: use of the Latin abbreviation '[sic]'. This introduces an unacceptable ambiguity. Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 112 and 35 U.S.C. § 101

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 15 provides for the use of the modifications A, B or C for the production of pharmaceutical preparations, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

7. Claim 15 is also rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

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Claim Rejections - 35 U.S.C. § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-3 and 15 and 16 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by DE 4200259 (cited by the applicants on page 1 of the specification, and whose US equivalent, US 5,384,330 (Dieter *et al.*) is cited in the IDS). As applicants admit on page 1 lines 24-29 of the specification, the compound of formula I is well known in the art, as is its use in pharmaceutical compositions. The three crystalline morphologies - A, B and C - of the compound of formula I are, therefore, inherent in the prior art. Applicants' admission, on lines 31-35 of page 1 of the specification, that crystallization produces different product mixes with regard to crystal size and form makes this clear.

Conclusion

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was

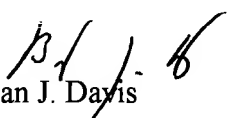
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made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Brian Davis whose telephone number is (703) 305-7129. The examiner can normally be reached M-F from 8 to 4:30.

12. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Geist, can be reached M-F from 8:30 to 5 at (703) 308-1701. The fax phone number for this Group is (703) 308-4556.

13. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.


Brian J. Davis

date: 5/24/99


GARY GEIST
SUPERVISORY PATENT EXAMINER
TECH CENTER 1000